

## ENZYMATIC THERAPY

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INTEGRATIVE THERAPEUTICS INC."

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## ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

February 28, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
GastroSoothe®*	Neutralizes stomach acid, so you receive immediate relief, but for temporary use.*	Calcium (from 500 mg of calcium carbonate), Deglycyrrizinated Licorice (DGL) (Glycyrrhiza glabra) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Dosler L.

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_2/28/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer 975 0162 LET 15797